STATE OF MAINE
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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GOVERNOR

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COMMISSIONER

# Memorandum

**TO:** Board of Environmental Protection

**FROM:** John James, Bureau of Remediation & Waste Management

**SUBJ:** Rulemaking; toxic chemical review

**DATE:** November 19, 2009

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I ask your approval to seek public comment on the following two rule chapters:

- Chapter 880, a proposed new rule setting forth the procedure for review and substitution of toxic chemicals in children's products; and
- Chapter 881, a companion rule that would allow the department to cover some of its review costs through fees paid by product manufacturers.

A preliminary draft of both chapters was shared with stakeholders and discussed with them over the course of four meetings this spring. Our facilitator's report on the stakeholder process is included in your packet material. To view the appendices to that report, including written comments from stakeholders, visit the department website at: http://www.maine.gov/dep/oc/safechem/.

**Statutory and regulatory references**

38 MRS §§1691 through 1699-B. A copy of the enacting bill—PL 2007, c. 643, eff. July 18, 2008—follows this memo.

**Description of rule - Chapter 880**

Chapter 880 sets forth the process by which you may designate and review "priority chemicals." The statute at 38 MRS §1694(1) requires you to name at least two priority chemicals by January 1, 2011, but your authority to designate priority chemicals is otherwise discretionary. There are several reasons why you may want to exercise that authority. The chief reason likely will be to facilitate the gathering of information on: i) the extent to which children may be exposed to the chemical as a result of its use in consumer products; and ii) the availability of safer alternatives.

*Notes*

1. Manufacturer disclosure of information on priority chemicals. The designation of priority chemicals is a powerful information gathering tool. It triggers an obligation on the part of manufacturers and distributors to disclose information on their use of the

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chemical in children's products. The type of information that must be disclosed will depend on the chemical. The department is not likely to need the same type and range of information for each priority chemical. Accordingly, the rule [see paragraph 2(D)(4) on page 4 and section 3 generally] provides for the scope of the required disclosure to be determined on a chemical by chemical basis.

2. Designation limited to "chemicals of high concern". From an estimated universe of almost 80,000 existing chemicals, the department and the Maine Center for Disease Control have identified about 1700 for inclusion on the Maine List of Chemicals of High Concern (CHC List). The list is published on the department website: http://www.maine.gov/dep/oc/safechem/highconcern/.

   A chemical must be on CHC List in order for the board to designate it as a priority chemical. The department, in turn, may include a chemical on the CHC List only if it has been identified by an authoritative governmental entity on the basis of credible scientific evidence as:

   - A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor;
   - Persistent, bioaccumulative and toxic; or
   - Very persistent and very bioaccumulative.

   The Legislature's decision to narrow the universe of chemicals in play by relying on existing governmental lists of known hazardous chemicals is a critical feature of the law. It is perhaps the most important factor in establishing a chemical review scheme that is workable for a small state with limited resources in that it avoids the need to revisit the reams of data and years of scientific scrutiny that undergird the existing lists.

3. Designation by rule required. Although the enacting legislation does not require it, section (2)(D) of the rule would require the designation of priority chemicals to be made through the adoption of a routine technical rule in accordance with the Maine Administrative Procedures Act (MAPA). This choice was made to guarantee, by bringing the rulemaking requirements of the MAPA to bear, that chemical manufacturers and other interested parties are: i) notified of a department proposal to designate one or more priority chemicals; and ii) have the opportunity to transmit facts, ideas and insights to the board and the department at the crucial time when we are deciding whether to proceed with the designation of a priority chemical. The requirement to designate by rule commits the department to a written explanation of the basis for its designation decision, including a written response to public comments on the proposed designation.

4. Handling of information claimed to be confidential. The statutes governing electronic waste [38 MRS §1610(6-A)(F)] and mercury-added products [38 MRSA §1661-A)(4)] explicitly allow information submitted by product manufacturers to be kept confidential under certain conditions. By contrast, the statute on toxic chemicals in children's products is silent on the handling of information claimed to be confidential. Implicit in this silence is a policy favoring public disclosure of information on the use of priority

chemicals in children's products, and a concomitant intent to limit the circumstances under which manufacturers can protect such information. Bringing this information into the public domain encourages the investigation and substitution of safer alternatives, which we believe was the Legislature's intent.

The Toy Industry Association has warned that information gathering will be impeded by appeals unless the rule sets forth a clear process by which manufacturers and distributors can designate certain required disclosures as confidential. Subsection 3(F) of the rule responds to the industry call for clear guidance by declaring certain information to be a public record upon submission to the department, while at the same time preserving industry's right to protect trade secrets. The information that the rule declares to be a public record is the same information that is required to be reported to the department under 38 MRS §1695(1):

- The identity of children's products that contain the priority chemical;
- Sales data on those products;
- The amount of the chemical in each unit of the product; and
- The function of the chemical in the product.

5. Applicability of law limited to "intentionally-added" chemicals. In response to stakeholder concerns, a definition of "intentionally-added" was inserted in section 1 of the rule to clarify that the law applies only to those children's products in which a priority chemical is intentionally added for a specific purpose during product formulation or manufacture. The term "intentionally-added" is used in the lead paragraphs to section 3 [disclosure] on page 4 of the rule and subsection 4(A) [product bans] on page 8.

   There is nothing in the legislative record or the words the Legislature used to suggest the legislature meant to regulate products in which a priority chemical is present as an impurity from the production process.

**Description of rule - Chapter 881**

Chapter 881 implements the department's authority under 38 MRS §1695(2)(C) and (3) to assess fees to cover:

- The department's reasonable costs in managing information submitted by manufacturers or distributors of children's products that contain the priority chemical; and
- The costs of an independent report on the availability of safer alternatives if, upon request by the department, a manufacturer fails to submit an acceptable alternatives assessment as defined in chapter 880(3)(B)(3).

The amount of the fee is determined on a case-by-case by apportioning the actual costs incurred by the department among those subject to the fee. Any person wishing to contest the amount of

the fee may file a petition with the commissioner. If the commissioner denies the petition in whole or part, the petitioner may file an appeal with you the board.

**Issue #1**

Perhaps the main unresolved stakeholder issue of concern is whether, though this rulemaking, limits should be placed on the department's authority to designate a priority chemical in the absence of demonstrated harm to children. It is undeniable that the statutory language on its face does not require a showing of actual harm. Industry stakeholders nevertheless have variously argued that:

- A demonstration of some actual harm should be a pre-requisite for designation of priority chemicals – *Consumer Specialty Products Association*;
- It would be premature to designate a priority chemical in the absence of research showing a direct relationship between the chemical and a negative impact on children – *Toy Industry Association*;
- Only those chemicals to which children are exposed at levels of concern should be considered for designation as priority chemicals- *American Chemistry Council*

The position of department staff is that, while the board is free to consider available evidence of actual harm as well as data on exposure levels, a demonstration of actual harm or exposure above a specified level of concern should not be made a pre-requisite to designation of priority chemicals, or to a product ban for that matter. To do so would render the law ineffective as an information gathering tool and vehicle for substitution of safer chemicals. The main purpose of designating a "priority chemical" is to trigger the manufacturer disclosure requirement and thereby facilitate gathering of additional information on that chemical so that the department can make an informed decision about the need for and appropriateness of a product ban.

The board may consider "dose, "levels of exposure", "margins of safety" and any other relevant data in its deliberations but the statute does not require a showing of actual harm or exposure at or above a specified "level of concern" as a prerequisite to a ban on the sale of children's products containing the chemical. As long as safer alternatives are shown to be available at comparable cost, the board can adopt a rule banning the sale of products that expose children to the chemical.

**Issue #2**

A secondary issue raised by industry participants in the stakeholder process is whether the rule should require, as pre-requisite to designation of a priority chemical, that the board prioritize the 1700+ chemicals on the CHC List. In other words, did the Legislature, in its choice of the word "priority", mean to suggest that the board should rank all 1700+ chemicals on the list to identify those that have the largest impact of human health (and therefore merit "priority" attention)?

This narrow reading of "priority" could not have been intended. It would frustrate the information gathering purpose of designation by, in effect, requiring that the department obtain

the information it seeks through designation as a pre-requisite to designation. We believe the Legislature used the word "priority" merely to signify a CHC chosen by the department for attention over the competing alternatives.

**Department recommendation**

We recommend you authorize us to arrange for public notice of the proposed rules, with a hearing date of December 17th and comment deadline of January 11th.

**Estimated presentation time.** 30 minutes